REMARKS

This document is submitted in response to the Office Action dated March 10, 2008 ("Office Action").

Upon entry of the proposed amendments, claims 1, 7, 8, and 16-27 will be pending. Claims 2-6 and 9-15 have been canceled without prejudice. Applicants have amended claims 1, 7 and 8, and added new claims 16-27. Support for the amendments and new claims can be found through out the specification, for example, at page 4, lines 9-14; page 16, lines 29-31; page 18, lines 28-29; page 19, lines 7-9; page 20, lines 31-33; page 21, lines 9-11; page 22, lines 33-35; and page 23, lines 5-6. No new matter has been added.

Information Disclosure Statement (IDS)

Applicants thank the Office for considering the references disclosed in the IDSs filed on various dates. The Office noted that the IDS filed May 22, 2006, disclosing U.S. Application Serial No. 10/542,682 ("the '682 application), has been lined through allegedly because it is not proper and a copy of the '682 application was not provided. See Office Action, at page 2, paragraph 2. Applicants respectfully point out that the '682 application was filed after the filing date of the present application, and therefore is not prior art. The purpose of the May 22, 2006 IDS is to notify the Office that the co-pending '682 application is related to the present application, in accordance with MPEP § 2001.06(b). Applicants presumed that the Office has access to the prosecution file of the '682 application. Thus, Applicants respectfully submit that the IDS filed May 22, 2006 is proper.

35 U.S.C. § 112, first paragraph (enablement)

The Office rejected claims 1-12 and 15 as allegedly failing to comply with the enablement requirement.

The Office appears to have concluded that the instant claims directed to an antibody against protein C or activated protein C (aPC) are not enabled because they fail to recite sequences for all six complementarity determining regions (CDRs). See the Office Action, at

page 3, lines 1-21. The Office further contended that claims 10-12, which recite the term "prevention," lack enablement because the specification fails to provide data showing that the claimed antibody could prevent a disease in 100% of the patients. See the Office Action, at page 4, lines 12-20.

Applicants respectfully disagree. However, for the purpose of expediting prosecution of this application, Applicants have amended claim 1 to recite a specific sequence for each of the six CDRs, and canceled claims 2-6, 9-12 and 15. Applicants note that new claims 20-27 are also directed to antibodies with specific CDR sequences. With respect to new claims 17-19, as described in the specification, methods known in the art can be used to determine the binding epitope of an antibody with the recited sequences, make an antibody that binds to the same epitope, and determine whether an antibody binds to such an epitope. See page 16, line 29, to page 17, line 16. Accordingly, skilled practitioners would know how to make and use the claimed antibodies without undue experimentation.

In view of the foregoing amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the present rejection under 35 U.S.C. § 112, first paragraph.

35 U.S.C. § 112, first paragraph (written description)

The Office rejected claims 1-12 and 15 as allegedly failing to comply with the written description requirement. Claims 2-6, 9-12, and 15 have been canceled.

The Office asserted that the specification fails to disclose a shared structure of the claimed genus of antibodies, and that the examples described in the specification are not sufficiently representative of the genus. See the Office Action, at page 6, lines 4-7. Applicants respectfully disagree. As stated in Example 13 of the Written Description Training Materials (Revision 1, March 25, 2008):

> ... the level of skill and knowledge in the art of antibodies at the time of filing was such that production of antibodies against a well-characterized antigen was conventional ... It does not appear that persons of skill in the art consider knowledge of the amino acid sequence of the variable regions critical for purposes of assessing possession of an antibody.

Example 14 further states: "As explained in Example 13 (Antibodies To A Single Protein), those of skill in the art of immunology would accept that an adequate description of a purified antigen would have put an inventor in possession of antibodies which bind to the purified antigen." In this case, at the time of filing, protein C and aPC were certainly well-characterized antigens. See, Susuki et al. (J. Biochem. (1985) 97:127-138), at page 128, first paragraph; and Grinnell et al (U.S. Pat. No. 6,037,322), at column 1, lines 19-44 (both references cited by the Office in this Office Action). Therefore, claims directed to antibodies that bind to protein C or aPC are adequately described, even if specific CDR sequences are not recited in the claims.

However, for the purpose of expediting prosecution of this application, Applicants have amended claim 1, as noted above, to recite all six CDR sequences of an antibody described in the specification. Similarly, new claims 20-27 recite the six CDR sequences of antibodies disclosed in the specification. New claims 17-19 are directed to an antibody that binds to the same epitope of protein C or aPC as an antibody with the recited CDR sequences. As noted above, as protein C and aPC are both well-characterized antigens, antibodies that bind to these antigens, regardless of the binding epitopes, are adequately described. Therefore, the instant claims satisfy the written description requirement.

Thus, Applicants respectfully request that the Office reconsider and withdraw the present rejection under 35 U.S.C. § 112, second paragraph.

35 U.S.C. § 102

Claims 1-6 and 8-12

The Office rejected claims 1-6 and 8-12 as allegedly anticipated by Suzuki et al. (J. Biochem. (1985) 97:127-138; "Suzuki"). Claims 2-6 and 9-12 have been canceled.

Applicants traverse with respect to the presently amended claims.

As discussed above, claim 1 is now directed to an antibody that includes specific heavy chain and light chain CDR sequences. While Suzuki describes various antibodies that bind human aPC, including one that inhibits the inactivation of aPC by protein C inhibitor, Suzuki does not disclose the sequences of any of its antibodies, as the Office acknowledged. See the

Office Action, at page 8, line 3. There is no reason to believe that any of the antibodies described in this reference has the sequences recited in claim 1. Thus, Suzuki does not anticipate claim 1 and its dependent claims. Nor does the reference anticipate new claims 20-27 drawn to antibodies with specific CDR sequences. With respect to new claims 17-19, Suzuki does not provide any information that would lead skilled practitioners to believe that any of its antibodies bind to the same epitope as an antibody with the recited CDR sequences. Thus, Suzuki fails to anticipate the present claims.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection under 35 U.S.C. § 102(b).

Claim 15

The Office rejected claim 15 as allegedly anticipated by Grinnell et al. (U.S. Pat. No. 6,037,322). Applicants do not agree, but have canceled the claim for the purpose of expediting prosecution of the application, rendering the rejection moot.

35 U.S.C. § 103

The Office rejected claims 1, 7, and 15 as allegedly obvious over Suzuki in view of Zuk et al. (U.S. Pat. No. 4,208,479; "Zuk"). Claim 15 has been canceled.

Applicants traverse with respect to amended claims 1 and 7.

The deficiencies of Suzuki are as discussed above. Zuk fails to remedy these deficiencies. The Office apparently cited Zuk for disclosing the advantages of placing reagents such as antibodies in kits. See the Office Action, at page 9, lines 15-18. Like Suzuki, there is nothing in Zuk to suggest Applicants' claimed antibody having the recited CDR sequences. Also like Suzuki, Zuk does not suggest the antibodies recited in new claims 17-27. Thus, Suzuki and Zuk, individually or combined, would not have led skilled practitioners to the claimed antibody.

In view of the foregoing, Applicants respectfully request that the Office reconsider and withdraw the present rejection under 35 U.S.C. § 103.

CONCLUSION

Applicants respectfully submit that all pending claims are in condition for allowance, which action is expeditiously requested. Applicants do not concede any positions of the Examiner that are not expressly addressed above, nor do Applicants concede that there are not other good reasons for patentability of the presented claims or other claims. The fee in the amount of $1050 for a three-month extension of time is being paid concurrently herewith on the Electronic Filing System (EFS) by way of Deposit Account authorization. Apply any other charges or credits to deposit account 06-1050, referencing Attorney's Docket No. 14875-138US1.

Respectfully submitted,

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